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European Medicines Agency

CTIS newsflash #11 - 22 April 2022

Introduction

Welcome to the 11th and final CTIS newsflash. This newsflash provides updates on key facts and figures regarding CTIS usage, as well as links to useful reference materials.

Note on the CTIS newsflash

As of May 2022, the weekly CTIS newsflash will be replaced with a monthly clinical trials metrics report, which will be available on the EMA website.

Key metrics

Metrics reported cover the period 11/04/2022-17/04/2022.

- **Total number of logins to CTIS:** 13,503
    - This metric represents the total sum of unique logins by individual users per day at the end of the period
- **Number of draft applications in CTIS:** 366
    - This metric counts the number of applications with status "Draft" in CTIS at the end of the period
- **Number of submitted applications in CTIS:** 31
- **Number of authorised applications in CTIS:** 2

News spotlight

The second clinical trial has been authorised through CTIS. It is the first clinical trial initiated via CTIS, i.e. a trial that was not previously ongoing under the Clinical Trials Directive which has begun under the regime of the Clinical Trials Regulation via submission to CTIS. The Member State concerned in the

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trial is Denmark. Patients, healthcare professionals and members of the public can see relevant information about the clinical trial in the CTIS public search such as the estimated recruitment start date, inclusion and exclusion criteria and sponsor details.

More information about CTIS and the CTIS public search is available at https://euclinicaltrials.eu/home.

Did you know?

CTIS allows sponsors to upload 'for publication' and 'not for publication' versions of certain documents, including the protocol and the investigator brochure. This functionality allows sponsors to protect personal data and Commercially Confidential Information (CCI) in CTIS by only providing such information in the 'not for publication' versions of the documents. Draft guidance on the protection of personal data and CCI in CTIS can be found below.

Protection of personal data and Commercially Confidential Information in CTIS – open consultation

To assist sponsors and authority users in fulfilling the transparency requirements set out in the Clinical Trials Regulation, EMA is preparing a dedicated guidance on the protection of personal data and CCI in CTIS.

EMA has published a draft of the guidance for open consultation to allow for wider stakeholder input and to account for experience gained in working with CTIS. The draft guidance and details on how to provide feedback can be found on the CTIS training and support page. The deadline to comment is **8 September 2022**.

A stakeholder workshop will be held during the public consultation period, further details will be shared in the Clinical Trials Highlights newsletter when available.

CTIS April bitesize talk topic changed to RFIs

The third CTIS bitesize talk will take place on 28 April. The topic of the bitesize talk has been changed to requests for information (RFIs) to provide sponsors with practical guidance on how to respond to requests for information received from Member States when they are evaluating an initial clinical trial application.

More information

Users can review Module 22 – Introduction to CTIS for public users for more information on the searching CTIS as a public user.

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